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EXAMINER
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MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/12/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	Application No. 10/633,404	Applicant(s) GOODE ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12/11/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 9, 14, 30, 35, 51 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-13, 15-17, 19-22, 24-29, 31-34, 36-38, 40-43, 45-50, 52-55, 57-59 and 61-65 is/are rejected.
- 7) ☒ Claim(s) 2, 18, 23, 39, 44 and 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/9/05</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Objections***

Claims 43 and 65 are objected to because of the following informalities:

On the second to last line of claim 43, "of such" should be replaced with "if such".

On the second to last line of claim 65, "of such" should be replaced with "if such".

Appropriate correction is required.

***Information Disclosure Statement***

The information disclosure statement filed 5/9/05 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The applicants should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. The applicants are requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

***Election/Restrictions***

Applicant's election without traverse of Groups A1, B2, and C1 in the reply filed on 12/11/06 is acknowledged.

In light of the applicants' amendments to claims 3, 24, and 45 the restriction requirement between groups A1-A3 is hereby withdrawn.

Claims 9, 14, 30, 35, 51, and 56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/11/06.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 12, 13, 15-17, 19-21, 43, 45-48, 54, 55, 57-59, and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,424,847 to Mastrototaro represents the most relevant prior art. Mastrototaro teaches a method for maintaining calibration of a substantially continuous analyte sensor, wherein a data stream is received from an analyte sensor, including at least one sensor data point (see entire document, especially col. 7, line 52-col. 8, line 60 of Mastrototaro). Reference data, including at least one reference data point is received from a reference analyte monitor (see entire document, especially col. 1, lines 39-45 of Mastrototaro). At least

one matched data pair is provided by matching reference analyte data to substantially time corresponding sensor data (see entire document, especially col. 11, lines 43-67 of Mastrototaro), forming a calibration set. A conversion function is created based on the calibration set, wherein the sensor data is converted into calibrated data using the conversion function (see entire document, especially col. 12, line 41-col. 15, line 37; col. 17, lines 30-34 of Mastrototaro). Subsequently, at least one additional reference data point is obtained and at least one new matched pair is created (see entire document, especially col. 12, lines 15-40; col. 15, lines 33-52 of Mastrototaro). The calibration set is evaluated with the new matched data pair is created wherein evaluating the calibration set includes at least ensuring that the matched data pairs in the calibration set span a predetermined time range or are no older than a predetermined value (see entire document, especially col. 12, lines 15-30 of Mastrototaro), wherein, since blood glucose reference readings are entered daily and calibration is performed daily, it is ensured that the matched data pairs in the calibration set are no older than a predetermined value of a day, or (see entire document, especially col. 15, lines 27-52 of Mastrototaro), wherein by using the paired calibration data points acquired most recently, 6 hours before, 12 hours before, and 18 hours before, it is ensured that the matched data pairs in the set span a predetermined time range. The calibration set is modified if such modification is required by the evaluation, wherein such modification involves the establishment of a new calibration set for the calculation of a new calibration factor (see entire document, especially col. 12, lines 15-30; col. 15, lines 27-45 of Mastrototaro).

Regarding claims 3-5 and 45-47, the step of evaluating said calibration set comprises evaluating the new matched data pair (see entire document, especially col. 12, lines 15-30; col. 15, lines 27-52 of Mastrototaro). With further regard to claims 4 and 5, evaluating the calibration set includes evaluating all of the matched data pairs in the calibration set and the new matched data pair or combinations of matched data pairs form the calibration set and the new matched data pair.

Regarding claims 6 and 48, the step of receiving sensor data comprises receiving a data stream from a long-term implantable analyte sensor (see entire document, especially col. 5, line 27-col. 6, line 41 of Mastrototaro).

Regarding claims 12 and 54, the reference analyte monitor comprises self-monitoring of blood analyte (see entire document, especially col. 11, lines 39-43 of Mastrototaro).

Regarding claims 13 and 55, the step of creating a conversion function comprises linear regression (see entire document, especially col. 12, line 41-col. 15, line 26 of Mastrototaro).

Regarding claims 15, 16, 57, and 58 the step of forming a calibration set comprise including between one and six matched data pairs, or at least two matched data pairs (see entire document, especially col. 15, lines 38-45 of Mastrototaro).

Regarding claims 17 and 59, the step of forming a calibration set comprises determining a value for  $n$ , where  $n$  is greater than one and represents the number of matched data pairs in the calibration set (see entire document, especially col. 12, line 41-col. 15, line 26 of Mastrototaro).

Regarding claims 19-21 and 61-63, a set of matching data pairs are determined from the evaluation and a calibration set is re-formed (See entire document, especially col. 12, lines 15-30; col. 15, lines 37-52 of Mastrototaro), wherein the set of matching data pairs are determined and the calibration set re-formed every time a new calibration occurs. With further regard to claims 20, 21, 62, and 63 the conversion function is recreated using the re-formed calibration set at each new calibration or determination of a new calibration factor and the sensor data is converted into calibrated using the re-created conversion function.

Regarding claims 43, 45-48, 54, 55, 57-59, and 61-63, Mastrototaro further describes a computer system for executing the method described above (see entire document, especially col. 6, lines 26-64 of Mastrototaro).

Claim 64 recites all of the method steps of claim 1. Therefore, Mastrototaro teaches all of the claimed elements of claim 64, as set forth above with regard to claim 1.

Claim 65 recites all of the claimed elements of claim 43 such that Mastrototaro teaches all of the claimed elements of claim 65, as set forth above with regard to claims 1 and 43.

As to the language in claims 1, 43, and 65, "from a reference analyte monitor", the applicants should note that the reference data is received from a reference analyte monitor wherein the monitor is a person, or alternatively, wherein the data is received via a user. In the apparatus claims, the applicants should note that "data from a reference analyte monitor" is "product by process" language, wherein the limitation is

evaluated based on the end-product, i.e. the data, rather than the process used to obtained the product. See MPEP § 2113.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 22, 24-27, 32-34, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrototaro, as applied to claims 1, 3-6, 12, 13, 15-17, 19-21, 43, 45-48, 54, 55, 57-59, and 61-65 above, and further in view of US Patent No. 6,122,536 to Sun et al. With respect to claim 22, Mastrototaro teaches the means for receiving reference data as receiving it as input from a user rather than receiving the data from the reference analyte monitor, as disclosed in the instant specification. However, Sun teaches the reference data for calibration of a glucose sensor being received directly from the reference analyte monitor (see entire reference, especially figs. 18a-c; col. 20, line 21-46 of Sun). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the means for receiving reference data of in place of that of Mastrototaro, as it would merely be the substitution of one known means of receiving reference data for another.

Regarding claims 11, 32, and 53, the step of receiving reference data form a reference analyte monitor comprises receiving within a receiver, internal communication



from a reference analyte monitor integral with the receiver, wherein the receiver 410 and reference analyte monitor 430 appear to be integral in figure 18a (see entire document, especially figs. 18a-c; col. 2, lines 21-46 of Sun).

Regarding claims 24-26, the step of evaluating said calibration set comprises evaluating the new matched data pair (see entire document, especially col. 12, lines 15-30; col. 15, lines 27-52 of Mastrototaro). With further regard to claims 4 and 5, evaluating the calibration set includes evaluating all of the matched data pairs in the calibration set and the new matched data pair or combinations of matched data pairs from the calibration set and the new matched data pair.

Regarding claim 27, the step of receiving sensor data comprises receiving a data stream from a long-term implantable analyte sensor (see entire document, especially col. 5, line 27-col. 6, line 41 of Mastrototaro).

Regarding claim 33 the reference analyte monitor comprises self-monitoring of blood analyte (see entire document, especially col. 11, lines 39-43 of Mastrototaro).

Regarding claim 34, the step of creating a conversion function comprises linear regression (see entire document, especially col. 12, line 41-col. 15, line 26 of Mastrototaro).

Regarding claims 36 and 37, forming a calibration set comprises including between one and six matched data pairs, or at least two matched data pairs (see entire document, especially col. 15, lines 38-45 of Mastrototaro).

Regarding claim 38, the step of forming a calibration set comprises determining a value from  $n$ , where  $n$  is greater than one and represents the number of matched data

pairs in the calibration set (see entire document, especially col. 12, line 41-col. 15, line 26 of Mastrototaro).

Regarding claims 40-42, a set of matching data pairs are determined from the evaluation and a calibration set is re-formed (See entire document, especially col. 12, lines 15-30; col. 15, lines 37-52 of Mastrototaro), wherein the set of matching data pairs are determined and the calibration set re-formed every time a new calibration occurs. With further regard to claims 42 and 42, the conversion function is recreated using the re-formed calibration set at each new calibration or determination of a new calibration factor and the sensor data is converted into calibrated using the re-created conversion function.

Claims 10, 31, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrototaro in view of Sun, as applied to claims 11, 22, 24-27, 32-34, and 53 above, and further in view of US Patent Application Publication 2002/0026111 to Ackerman. Mastrototaro is silent as to the communication scheme between the external calibration device 410-440 and the control module 300, which module executes determination of the sensor 330, except to state that telemetry is used (see entire document, especially figs. 18a-c; col. 20, lines 21-42; col. 21, lines 13-21 of Sun). However, Ackerman teaches that telemetry in an analyte sensing system may be effected via wireless link (see entire document, especially paragraph 79 of Ackerman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use wireless communication as the telemetric communication in

Mastrototaro, as modified by Sun, since Mastrototaro, as modified, teaches using telemetry, and Ackerman describes wireless communication as an appropriate form of such telemetry.

Claims 7, 8, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrototaro, as applied to claims 1, 3-6, 12, 13, 15-17, 19-21, 43, 45-48, 54, 55, 57-59, and 61-65 above, and further in view of US Patent Application Publication No. 2003/0130616 to Steil et al. Mastrototaro is silent as to filtering of the sensor data. However, Steil teaches filtering 400, 402 or algorithmically smoothing the data before transmitting the sensor data to the controller, wherein the controller receives the sensor data and calibrates it (see entire document, especially figs. 1, 10, and 16; paragraph 238 and 243 of Steil). Steil further teaches an analyte monitoring system and method wherein the sensor data 16 is received and then filtered or algorithmically smoothed before calibration (see entire document, especially figs. 1, 3b, 8c; paragraph 238 of Steil). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to either receive an algorithmically smoothed data stream or for the step of receiving to comprise algorithmically smoothing the data stream, since Mastrototaro teaches sensing analyte values, and Steil teaches such algorithmic smoothing (filtering) detect and minimizes the effects of anomalous sensor values in analyte sensors (see entire document, especially paragraph 243 of Steil).

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrototaro in view of Sun, as applied to claims 11, 22, 24-27, 32-34, and 53 above, and further in view of and further in view of US Patent Application Publication No. 2003/0130616 to Steil et al. Mastrototaro, as modified, is silent as to filtering of the sensor data. However, Steil teaches filtering 400, 402 or algorithmically smoothing the data before transmitting the sensor data to the controller, wherein the controller receives the sensor data and calibrates it (see entire document, especially figs. 1, 10, and 16; paragraph 238 and 243 of Steil). Steil further teaches an analyte monitoring system and method wherein the sensor data 16 is received and then filtered or algorithmically smoothed before calibration (see entire document, especially figs. 1, 3b, 8c; paragraph 238 of Steil). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to either receive an algorithmically smoothed data stream or for the step of receiving to comprise algorithmically smoothing the data stream, since Mastrototaro, as modified, teaches sensing analyte values, and Steil teaches such algorithmic smoothing (filtering) detect and minimizes the effects of anomalous sensor values in analyte sensors (see entire document, especially paragraph 243 of Steil).

***Allowable Subject Matter***

Claims 2, 18, 23, 39, 44, and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 2, 23, and 44, the prior art of record fails to teach or fairly suggest a method or system for maintaining calibration of a substantially continuous analyte sensor, wherein the step of evaluating said calibration set further comprises at least one of evaluating a rate of change of the analyte concentration, evaluating a congruence of respective sensor and reference data in said matched data pairs, and evaluating physiological changes, in combination with all of the other limitations of the claims.

Regarding claims 18, 39, and 69, the prior art of record fails to teach or fairly suggest a method or system for maintaining calibration of a substantially continuous analyte sensor, wherein the step of determining a value for n is determined as a function of the frequency of the received reference data points and signal strength over time, in combination with all of the other limitations of the claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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*Myth Anderson*